JAN 4 2006

K053486



**510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92**

(a) (1) **Submitted by:**

HOFFRICHTER GmbH
Mettenheimer Strasse 12/14
D-19061 Schwerin
Germany
Tel.: +49-385-39925-0
Fax: +49-385-39925-25
E-mail: info@hoffrichter.de

**Contact Person:** Norbert Küchemann

**Position/Title:** Sales Manager

**Date of Preparation:** December 12, 2005

(2) **Trade Name:** TREND 200 CPAP device with TRENDset PC Software

**Common/Classification Name:** VENTILATOR, CONTINUOUS, NON-LIFE-SUPPORTING;

**Product Code(s):** BZD, 21 CFR §868.5905

**Class:** Class II

(3) **Predicate Device(s):** • TREND 110 CPAP Device (K041035)

**Reason for Submission:** Device modification to TREND 110

(4) **Description of Device:**

The Hoffrichter *TREND 200* device provides mono-level CPAP treatment levels over the clinician settable range of 4 to 18 $cmH_2O$.

The *TREND 200* CPAP device is modification of the TREND 110 CPAP device which adds the following features:

- Real time clock with wake-alarm support.
- Audible tone generator with audible alert functions.
- EEPROM capacity increased to store times of device use (patient compliance data).
- Serial port which can transmit the stored times of device use.
- *TRENDset* PC software which may be used by the clinician to communicate to the *TREND 200* to acquire, display, and print the patient compliance data (times of use).
- DC power inlet for alternate power source option.

The *TREND 200* CPAP device is provided in a compact lightweight enclosure for easy bedside use, and utilizes the same form factor and accessories as the *TREND 110*. A 2 x 16 character LCD display with keys on the operator panel provides the user with displayed information about the treatment level as well as access to menus for soft-start ramp, clinical prescription (set by doctor, PIN code protected), day/date/wake-alarm, and hours of operation. *TREND 200's* power supply automatically supply adapts to regional mains voltage (115 to 230 VAC).

Standard accessories include treatment tubing with integrated measurement tube and headgear. Commercially available masks and swivels are specified.

As in the *TREND 110*, *TREND 200* treatment pressure is measured as close as possible to the patient mask by means of a measuring tube integrated into the therapy tubing. This maximizes accuracy and control of pressure and accounts for losses due to the therapy delivery circuit.

Hoffrichter CPAP devices are prescription use devices, and are not intended for life supporting or life sustaining applications.

(5) **Intended use:**

Obstructive sleep apnea (OSA) is a condition caused by closing of the upper airway during sleep. The uvula and soft pallet collapse on the back wall of the upper airway, and when the tongue moves back, the airway is temporarily sealed, causing disruptions in normal respiration and sleep.

Continuous Positive Airway Pressure (CPAP) is an effective treatment for OSA. CPAP devices treat the condition by supplying a constant positive pressure to the airway, most commonly via the nasal passages, in order to prevent the collapse of the soft tissue of the uvula and soft palate during sleep.

**Indications for Use:**

The TREND 200 device is for treatment of obstructive sleep apnea (OSA) in adult patients weighing at least 30 kg. These devices are not intended for use with ventilator-dependent patients.

The TREND 200 device provides continuous positive airway pressure.

The TRENDset PC Software is a program for reading the TREND CPAP device patient compliance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 4 2006

Hoffrichter GmbH
C/O Mr. Stephen H. Gorski
Submission Correspondent/USA Agent
S65 IMAGENIX, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K053486
Trade/Device Name: Hoffrichter TREND 200 CPAP Device
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 12, 2005
Received: December 15, 2005

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

**510(k) Number** (if known):

**Device Name:** Hoffrichter TREND 200 CPAP Device

**Indications for use:**

The TREND 200 device is for treatment of obstructive sleep apnea (OSA) in adult patients weighing at least 30 kg. These devices are not intended for use with ventilator-dependent patients.

The TREND 200 device provides continuous positive airway pressure.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible], General Hospital,
Infection Control, Dental Devices
[illegible] 2003436